Secretary of the State File Number
6361

Regulation of the

Department of Consumer Protection

Concerning

Medical Marijuana Laboratory Testing

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

Posted to the Connecticut eRegulations System on **June 13, 2022**

EFFECTIVE DATE
June 13, 2022

Approved by the Attorney General on
March 29, 2022

Approved by the Legislation Regulation Review Committee on
May 24, 2022

Electronic copy with agency head certification statement electronically submitted to and received by the Office of the Secretary of the State on
May 25, 2022

Form ICM-ECOPY (NEW 6/2015)
State of Connecticut
Secretary of the State

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES
This form should be used only for regulations first noticed *on and after March 23, 2015.*

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the
Department of Consumer Protection
Concerning
Medical Marijuana Laboratory Testing

Approved by the Legislative Regulation Review Committee: **May 24, 2022**
eRegulations System Tracking Number: **PR2021-042**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto set my hand on **May 25, 2022**.

Julianne Avallone
Legal Director
Department of Consumer Protection

State of Connecticut
Regulation of
Department of Consumer Protection
Concerning
Medical Marijuana Laboratory Testing

Section 1. Section 21a-408-60 of the Regulations of Connecticut State Agencies is amended to read as follows:

Sec. 21a-408-60. Laboratory testing

(a) Immediately prior to manufacturing any marijuana product or packaging raw marijuana for sale to a dispensary, a producer shall segregate all harvested marijuana into homogenized batches.

(b) A producer shall make available each such batch at the production facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

(c) From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a dispensary facility, until the laboratory provides the results from its tests and analysis, the producer shall segregate and withhold from use the entire batch of marijuana, except the samples that have been removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a dispensary facility prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any marijuana upon the completion of any testing, use, or research. If a laboratory disposes of marijuana, the laboratory shall comply with section 21a-408-66 of the Regulations of Connecticut State Agencies.

(e) If a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the producer shall dispose of the entire batch from which the sample was taken in accordance with section 21a-408-66 of the Regulations of Connecticut State Agencies.

(1) For the purposes of the microbiological test, a marijuana sample of not less than one gram shall be [deemed to have passed if it satisfies the standards set forth in Section 2023 of United States Pharmacopeia for all raw products and Section 1111 of the United States Pharmacopeia for all dosage forms other than raw product, which can be obtained at http://www.usp.org] tested using a molecular method that is certified for identifying microbiological DNA and approved by the Association of Official Analytical Collaboration (AOAC) International and includes quantitative polymerase chain reaction (qPCR), or an alternative method approved by the department. For the purposes of the microbiological test, such samples shall be deemed satisfactory if (A) E. coli, shiga toxin producing E. coli, L. monocytogenes, and salmonella spp. are not detected, (B) the total aerobic microbial count and total combined yeast and mold count are each equal to or less than 10^5 cfu/g or ml, and (C) the pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* are not detected. Laboratories designated as medical marijuana laboratories as of July 1, 2021 shall have one hundred eighty days from *{insert effective date of this section}* to obtain the

necessary equipment and accreditation to comply with the qPCR testing method but shall otherwise meet the standard set forth in this subdivision.

(2) For the purposes of the mycotoxin test, a marijuana sample shall be deemed [to have passed if it meets] satisfactory if not less than one half of one gram is tested using a liquid chromatography-mass spectrometry (LC-MS) or an enzyme-linked immunosorbent assay (ELISA) method approved by the Association of Official Analytical Collaboration (AOAC) International, Federal Food and Drug Association or United States Pharmacopeia, or an alternative method approved by the department, and such sample contains less than 20 micrograms per kilogram of each of the following [standards:] mycotoxins: aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A. [

Test	**Specification**
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance]

(3) For the purposes of the heavy metal test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Metal	**Natural Health Products Acceptable limits uG/KG BW/Day**
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

(4) For the purposes of the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.

(f) If a sample of marijuana passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a dispensary facility.

(g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the producer. In addition, the

laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-72 of the Regulations of Connecticut State Agencies.

(h) A producer shall provide to a dispensary facility the laboratory test results for each batch of marijuana used in a product purchased by the dispensary facility. Each dispensary facility shall have such laboratory results available upon request to qualifying patients, [primary] caregivers and physicians or APRNs who have certified qualifying patients.

Statement of Purpose

The purpose of this regulation is to update microbial testing standards for medical marijuana to better protect public health and safety. This proposed language creates laboratory testing standards that: (i) prohibit cannabis from entering the market if it has specific microorganisms that are shown to be harmful when inhaled, and (ii) allows for a greater general limit of microorganisms that may be beneficial or not harmful. This proposed change will create clarity and consistency for laboratories and medical marijuana patients.

Form Agency-Cert-PR-TA-ICM (Rev 11/2017)
State of Connecticut
Secretary of the State

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES
This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION

Department of Consumer Protection

Proposed Regulation Concerning

Medical Marijuana Laboratory Testing

eRegulations System Tracking Number **PR2021-042**

I hereby certify the following:

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities: **Conn. Gen. Stat. section 21a-408r**

For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.

(2) As permitted by Section 4-168(h) of the *Connecticut General Statutes*, the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on **and N/A**.

For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)

(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on **December 29, 2021**.

(4) *(Complete one)* ☒ No public hearing held or was required to be held. **OR** ☐ One or more public hearings were held on: **N/A**.

(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on **March 17, 2022**.

(6) *(Complete one)* ☐ No comments were received. **OR** ☒ Comments were received and the agency posted the statements specified in subdivisions (1) and (2) of CGS Section 4-168(e) to the eRegulations System website on **March 17, 2022**.

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **March 17, 2022**.

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(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, **the final regulation shall be effective**

(Check one and complete as applicable)

☒ When posted to the eRegulations System website by the Secretary of the State.

OR ☐ On _____
(Date must be a specific calendar date not less than 11 days after submission to the Secretary of the State)

	Legal Director	March 17, 2022
SIGNED *(Head of Board, Agency or Commission, or duly authorized deputy)*	OFFICIAL TITLE	DATE

OFFICE OF THE ATTORNEY GENERAL
REGULATION CERTIFICATION

Agency: Connecticut Department of Consumer Protection

***REGULATION NUMBER* PR2021-042**

This Regulation is hereby APPROVED by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: March 29, 2022

Signed: Joseph Rubin, Asst. Dep. A.G. Digitally signed by Joseph Rubin, Asst. Dep. A.G. Date: 2022.03.29 09:17:41 -04'00'

Joseph Rubin
Assistant Deputy Attorney General
Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator James Maroney
Senate Chair

Representative Nicole Klarides-Ditria
House Chair

Official Record of Committee Action

May 24, 2022

Agency:	Department of Consumer Protection
Description:	Medical Marijuana Laboratory Testing
LRRC Regulation Number:	2022-007
eRegulation Tracking Number:	PR2021-042

The above-referenced regulation has been

Approved with Technical Corrections

by the Legislative Regulation Review Committee in accordance with CGS Section 4-170.

Kirstin L. Breiner
Committee Administrator

State of Connecticut
Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Consumer Protection concerning Medical Marijuana Laboratory Testing
eRegulations System Tracking Number PR2021-042
Legislative Regulation Review Committee Docket Number 2022-007

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4-172 on May 25, 2022.

Said regulation is assigned Secretary of the State File Number 6361.

The effective date of this regulation is June 13, 2022.

Denise W. Merrill
Secretary of the State
June 13, 2022

By:

/s/ Christopher R. Drake
Christopher R. Drake
Director, Business Services Division